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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/717,379 | 11/19/2003 | Bruce M. Frankel | 7177.US.01 | 6700 |

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| EXAMINER |
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RAMANA, ANURADHA

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| ART UNIT | PAPER NUMBER |
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3733

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/717,379 | Applicant(s) FRANKEL ET AL. | |
| | Examiner Anu Ramana | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Melker et al. (US 5,484,442).

Melker et al. disclose a threaded needle or "bone tap" having an axial passageway 31, one or more openings or "fenestrations" 34, and threads shaped or "configured" to ensure that the needle is stable and prevents leakage once inserted (Figs. 1 and 8, col. 3, lines 27-67, col. 4, lines 1-48, col. 5 and col. 6, lines 1-8).

Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathis et al. (US 6,048,343).

Mathis et al. disclose a system for forming an opening in bone including a screw or "tap" 100 with a plurality of openings or fenestrations 122 spaced at regular intervals along the shaft, a head 112 with a suitably shaped opening to receive a tool or driver such as an Allen-type wrench, an adapter or "fluid port" 142 and a fluid delivery system such as a syringe with cement (col. 2, lines 29-67 and col. 3, lines 1-34).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melker et al. (US 5,484,442) in view of Stednitz (US 4,537,185).

Melker et al. disclose all elements of the claimed invention except for at least one flute in the threads.

Stednitz teaches making a threaded body self-tapping by providing at least two flutes on the shaft of the threaded body (Fig. 3 and col. 2, lines 40-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided flutes on the threaded shaft of the Melker et al. device, as taught by Stednitz, to make the device self-tapping.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) in view of Stednitz (US 4,537,185).

Mathis et al. disclose all elements of the claimed invention except for at least one flute in the threads.

Stednitz teaches making a threaded body self-tapping by providing at least two flutes on the shaft of the threaded body (Fig. 3 and col. 2, lines 40-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided flutes on the threaded shaft of the Mathis et al. device, as taught by Stednitz, to make the device self-tapping.

Claims 9-10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) in view of Simonson (US 6,159,179).

Mathis et al. disclose all elements of the claimed invention except for at least one dilator. See previous discussion of Mathis et al.

Simonson teaches using a cannula or dilator to perform a surgical procedure to limit tissue disruption and for a small incision (col. 1, lines 17-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a dilator, as taught by Simonson, in the system of Mathis et al., to limit tissue disruption.

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The method steps of claims 15-19 are performed when the Mathis et al. bone tap is placed through a dilator to introduce fluid into bone.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) and Simonson (US 6,159,179), as applied to claim 9, further in view of Heini (US 4,903,691).

The combination of Mathis et al. and Simonson disclose all elements of the claimed invention except for a driver having a resilient member.

Heini teaches a driver having a resilient tab or collet 11 that is used to engage a screw head in order to drive the screw in a safe and efficient manner (Fig. 6 and col. 9, lines 14-68).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a driver, as taught by Heini, to drive the screw in the system of the combination of Mathis et al. and Simonson, in a safe and efficient manner.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorek (US 6,752,809) in view of Foley et al. (US 5,902,231).

Gorek discloses a method of introducing a fluid into bone during spinal surgery including the steps of: advancing a bone tap into bone, introducing fluid to the bone through at least one of the openings, allowing fluid to spread into the bone and introducing a bone fastener into an opening formed by the bone tap (Fig. 3d, col. 5, lines 35-67, cols. 6 and 7 and col. 8, lines 1-63).

Gorek discloses all elements of the claimed invention except for using minimally invasive surgical procedures to access bone.

Foley et al. teach minimally invasive surgical techniques for spinal applications to reduce post-operative recovery time by providing a cannula that defines a working channel for the particular surgical procedure being performed (col. 3, lines 26-44 and col. 4, lines 58-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the method of Gorek, using a minimally invasive approach to the spine, as taught by Foley et al., to reduce post-operative recovery time.

Response to Arguments

Applicant's arguments in the response filed on January 18, 2006 have been fully considered but are not persuasive with respect to claims 1-8 for the following reasons.

Regarding the limitation, "for introducing fluid into a vertebra," and "configured to introduce fluid into the vertebra," and "facilitates insertion of the body into vertebra" it is noted that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Melker et al. and Mathis et al. clearly disclose Applicants' claimed invention as discussed in the rejections above.

Applicant's arguments with respect to claims 9-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

Anuradha Ramana
March 31, 2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER